

### **REMARKS**

Reconsideration and withdrawal of the rejection of claim 28, in view of the amendments and remarks herein, is respectfully requested. Claim 28 is amended and as a result, claim 28 is pending in this application.

Support for the amendment to claim 28 can be found throughout the specification. For example, the specification, at page 9, lines 5-6 and 14-17, discloses that the controlled delivery system includes a matrix forming material and an organic solvent, respectively. The specification, at page 9, lines 6-9, discloses that the matrix forming material can be made from a biocompatible polymer, copolymer or non-polymeric material that is substantially insoluble in aqueous fluids such as water or body fluids. The specification, at page 9, lines 14-17, further discloses that upon contacting an aqueous environment, such as a patient's body fluids, the matrix forming material coagulates or precipitates to form a solid implant. This means that the non-polymeric material is a solid at body temperature.

Thus, the amendment to claim 28 is supported by the specification as filed, and no new matter has been introduced.

### **§112 Rejection of the Claims**

Claim 28 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleged that it is unclear whether the "non-polymeric material" is the previously recited organic solvent or a third component as the claim language may be interpreted to include the recited solvent in claim 1. Applicant respectfully traverses for the reasons discussed below. However, to advance prosecution, Applicant has amended claim 28 as discussed herein.

Applicant traverses the Examiner's rejection for the following reasons. Claim 28 depends from claim 1, which recites a composition for delivering a biologically active agent that comprises an emulsion of a biologically active mixture and a controlled release formulation. Claim 1 further specifies that the controlled release formulation comprises a polymer and an

organic solvent. The specification, at page 9, lines 5-6 and 14-17, discloses that the controlled delivery system includes a matrix forming material and an organic solvent, respectively. The specification, at page 9, lines 6-9, discloses that the matrix forming material can be made from a non-polymeric material that is substantially insoluble in aqueous fluids such as water or body fluids. The specification, at page 9, lines 14-17, further discloses that upon contacting an aqueous environment, such as a patient's body fluids, the organic solvent dissipates or disperses into the surrounding aqueous fluids, and the matrix forming material coagulates or precipitates to form a solid implant. Thus, it is clear that the non-polymeric material of claim 28 is not the previously recited organic solvent.

To advance prosecution and to clarify the subject matter of the invention, Applicant has amended claim 28 to recite "a composition of claim 1, wherein the thermoplastic polymer is in mixture with a pharmaceutically acceptable, biodegradable non-polymeric material that is substantially insoluble in aqueous or body fluid and is a solid at body temperature." The amendment to claim 28 is not intended to concede to the correctness of the Examiner's position or to prejudice the claim prior to amendment. As amended, claim 28 clearly indicates that the non-polymeric material is distinct from the organic solvent recited in claim 1.

Therefore, reconsideration and withdrawal of the rejection of claim 28 is respectfully requested.

*Allowable Subject Matter*

Claims 1-3, 14-16, 19 and 29-32 were allowed. The Examiner indicated that claim 16 was allowed. Applicant notes that claim 16 was cancelled. Thus, claims 1-3, 14-15, 19 and 29-32 were allowed.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

RICHARD L. DUNN

By his Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

(612) 373-6939

Date May 8, 2006

By Albin J. Nelson  
Albin J. Nelson  
Reg. No. 28,650

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8th day of April, 2006.

Dawn M. Boyle

Name

Dawn M. Boyle

Signature